

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

IN RE APPLIED THERAPEUTICS SECURITIES
LITIGATION

Case No. 1:24-cv-09715 (DLC) (VF)

CLASS ACTION

ORAL ARGUMENT REQUESTED

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT
RICCARDO PERFETTI'S MOTION TO DISMISS THE
CONSOLIDATED AMENDED CLASS ACTION COMPLAINT**

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Dr. Riccardo Perfetti, M.D., Ph.D. respectfully submits this Memorandum of Law in Support of his Motion to Dismiss the Consolidated Amended Class Action Complaint (“CAC”) (ECF No. 72), pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, filed in this action by Lead Plaintiff Dr. Martin Dietrich (“Plaintiff”).

PRELIMINARY STATEMENT

At its core, this case is about a plethora of allegedly false and misleading statements made or caused to be made to the investing public by Applied Therapeutics, Inc. (“Applied” or the “Company”) and by Dr. Shoshana Shendelman—Applied’s founder and former CEO, President, Secretary, and Chair of the Board of Directors. These statements concern the Company’s New Drug Application (“NDA”) for govorestat (also known as AT-007) submitted to the U.S. Food and Drug Administration (“FDA”) in December 2023 and rejected by the FDA in November 2024.

This case is not about Dr. Perfetti, the Company’s Chief Medical Officer (“CMO”) and the only other individual defendant. To be sure, Plaintiff does not allege a single statement by Dr. Perfetti—not *one*—about the NDA or the regulatory process, let alone an actionable statement. Nor does Plaintiff plausibly allege any manipulative or deceptive acts by Dr. Perfetti that would make him a participant in Dr. Shendelman’s alleged scheme, or that he somehow controlled Applied or Dr. Shendelman and is therefore liable for their alleged violations.

The CAC alleges 71 misstatements, but only three are even allegedly attributed to Dr. Perfetti.

First, Plaintiff claims Dr. Perfetti is responsible for statements in an August 7, 2024 financial analyst report by RBC Capital Markets (the “RBC Report”) describing what “the company emphasized” (not Dr. Perfetti) about its disclosure that day regarding the Phase III trial

for govorestat. *See* Declaration of Jeffrey J. Chapman in Support of Defendant Perfetti’s Motion to Dismiss (“Chapman Decl.”) Ex. 1; CAC at ¶¶ 207-208.¹

Second, Plaintiff claims the contents of 15 slides used by a panelist (not Dr. Perfetti) at a September 4, 2024 Annual Symposium of the Society for the Study of Inborn Errors of Metabolism (the “SSIEM Slides”) are attributable to him without any well pled facts indicating that he created the slides or spoke about the matters addressed in the slides. *See* Chapman Decl. Ex. 2; CAC at ¶¶ 223-225.

Finally, Plaintiff takes issue with a November 6, 2024 article in *The Journal of Clinical Pharmacology* (the “November 2024 Article”) concerning the results of the March 2021 randomized, double-blind, placebo controlled study evaluating the safety and efficacy of AT-007 in pediatric patients with Classic Galactosemia (the “Pediatric Study”).² *See* Chapman Decl. Ex. 3; CAC at ¶¶ 249-252. The November 2024 Article was authored by 18 medical professionals (including Dr. Perfetti), several of whom are not affiliated with the Company.³ *See* Chapman Decl. Ex. 3.

Plaintiff’s claims against Dr. Perfetti are not even based on the contention that the statements attributed to him in the RBC Report, SSIEM Slides, and November 2024 Article are themselves materially false. Rather, they rest on the allegation that, in making these statements (two of which he did not make), Dr. Perfetti fraudulently failed to disclose: (i) that certain

¹ The facts herein are taken from the CAC and documents it incorporates by reference. *See, e.g., Kleinman v. Elan Corp.*, 706 F.3d 145, 152 (2d Cir. 2013) (“We may also ‘consider any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference, . . . and documents possessed by or known to the plaintiff and upon which it relied in bringing the suit.’”).

² Evan Bailey et al., *Results of the ACTION-Galactosemia Kids Study to Evaluate the Effects of Govorestat in Pediatric Patients with Classic Galactosemia*, *Journal of Clinical Pharmacology* 1 (Nov. 6, 2024), Chapman Decl. Ex. 3.

³ *Id.*

participants in the Pediatric Study received a lower dosage of govorestat than they should have received during a brief period of the dose-escalation period (not the long-term clinical efficacy and safety outcomes portion) of the Pediatric Study (the “Dosing Errors”);⁴ (ii) the NDA did not include a description and analysis of the Dosing Errors or the clinical data relating to the Dosing Errors (the “Dosing Errors Clinical Data”); and (iii) that in March 2024, the Company’s independent contract research organization deleted electronic data for 47 subjects of the Pediatric Study (the “Study Data Deletion”). CAC at ¶¶ 3, 4, 10, 208, 225, 250-252.

Notably absent from the CAC is any allegation, much less one pled with the particularity required under Federal Rule of Civil Procedure 9(b), that Dr. Perfetti *actually made* any statement in the RBC Report or the SSIEM Slides. Plaintiff contends that Dr. Perfetti violated Section 10(b) of the Securities Exchange Act of 1934 (“Exchange Act”) [15 U.S.C. § 77j(b)]; and Rule 10b-5(b) thereunder [17 C.F.R. § 240.10b-5(b)] based on these two statements, notwithstanding clear Supreme Court precedent to the contrary holding only the “maker” of a misstatement is liable under Section 10(b) of the Exchange Act and Rule 10b-5(b) thereunder. *See Janus Capital Grp. v. First Deriv. Traders*, 564 U.S. 135, 142-44 (2011).

With respect to the November 2024 Article, Plaintiff does not allege that the Pediatric Study data or results discussed in the article were inaccurate or relate in any way to the Dosing Errors, Dosing Errors Clinical Data, or Study Data Deletion. Nor does Plaintiff allege the Pediatric Study results contain any representation regarding the contents of the NDA. Devoid from Plaintiff’s allegations is the close nexus between the statements allegedly made by Dr. Perfetti and his alleged omissions necessary to impose a duty to disclose.

⁴ *Id.* at 2.

Further, when Plaintiff asserts Dr. Perfetti misled investors about the results of the Pediatric Study and govorestat's regulatory prospects, *see* CAC at ¶¶ 5, 38, 39, 60, 70, 72, 75, 208, 225, 252, he fails to allege that Dr. Perfetti made any statement about the NDA or regulatory process, or plead facts demonstrating that Dr. Perfetti acted with scienter with respect to any statement or action. Plaintiff refers to certain securities transactions, *see id.* at ¶ 304, but they were small, routine, and for tax purposes—and none were suspicious in timing or nature. The CAC contains no allegation—not one—concerning emails, conversations, or documents reflecting any improper motive or fraudulent intent on the part of Dr. Perfetti, much less any reason for him to doubt the NDA would be approved.

Plaintiff's effort to broadly attribute damages to the FDA's November 27, 2024 Complete Response Letter ("CRL") denying the NDA and the Warning Letter that followed does not adequately plead loss causation. None of these disclosures corrected, or revealed the truth of, any alleged misstatement by Dr. Perfetti. Rejection of the NDA communicated no more than the occurrence of a known regulatory risk, and, in any event, the CAC does not allege Dr. Perfetti ever publicly discussed the NDA or its likelihood of approval.

Despite Dr. Perfetti having nothing to do with—e.g., no role in drafting, disseminating, certifying, or otherwise signing—the contents of any of the 68 alleged misstatements by only Dr. Shendelman or the Company in the CAC, Plaintiff has alleged he engaged in a scheme to help Dr. Shendelman deceive the investing public and artificially inflate and maintain the market price of Applied's stock. Plaintiff tries to manufacture a scheme by repeatedly offering the conclusory allegation that Dr. Perfetti "knew, or recklessly disregarded, that [the Company] would be, and in fact had already been, subject to an FDA investigation in connection with the NDA, and as such there was a significant risk that the Dosing Errors and Dosing Errors Clinical Data would be

discovered by the FDA” and the NDA would be denied. *Id.* at ¶ 159. In doing so, Plaintiff merely repackages his misstatement allegations, lacking a separate, inherently deceptive act performed by Dr. Perfetti needed to sufficiently plead scheme liability.

Finally, Plaintiff’s threadbare allegation that Dr. Perfetti is a control person by virtue of his title, and conclusory allegation that he was involved in drafting, producing, reviewing and/or disseminating the complained of statements, is likewise insufficient to state a claim for violations of Section 20(a) of the Exchange Act [15 U.S.C. § 78t(a)].

For these reasons, explained in more detail below, the claims in the CAC against Dr. Perfetti should be dismissed with prejudice.

STANDARD OF REVIEW

To survive a motion to dismiss under Rule 12(b)(6), “a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 547 (2007)). Although the Court must take as true all factual allegations in the CAC, it is “not bound to accept as true a legal conclusion couched as a factual allegation” or “naked assertion[s] devoid of further factual enhancement.” *Id.* (internal quotation marks and citations omitted).

In addition to the requirement to allege “facts” establishing a “plausible” claim under *Twombly*, 550 U.S. at 547, and *Iqbal*, 556 U.S. at 678, a plaintiff alleging securities fraud or falsities in the Southern District of New York must also satisfy the heightened pleading requirements of both Rule 9(b) and the Private Securities Litigation Reform Act (“PSLRA”). *See ECA, Local 134 IBEW Joint Pension Tr. of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 196 (2d Cir. 2009). Rule 9(b) requires a plaintiff to plead the circumstances constituting fraud or mistake “with particularity.” Fed. R. Civ. P. 9(b); *see Chill v. Gen. Elec. Co.*, 101 F.3d 263, 267

(2d Cir. 1996). The heightened pleading requirements under the PSLRA requires a plaintiff to (i) “specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading” and (ii) “with respect to each [alleged] act or omission . . . state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind” (*i.e.*, scienter). Section 20D(b)(1), (2) of the Exchange Act [15 U.S.C. §§ 78u-4(b)(1), (2)]. The Second Circuit requires that a securities fraud complaint must (1) specify the fraudulent statements, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent. *Rombach v. Chang*, 355 F.3d 164, 170 (2d Cir. 2004). Thus, “[a]legations that are conclusory or unsupported by factual assertions are insufficient.” *ATSI Commc’ns*, 493 F.3d at 99. Courts should dismiss any complaint that “simply offers a generalized allegation.” *Id.* at 106.

ARGUMENT

I. The CAC Fails to State a Claim Against Dr. Perfetti Under Section 10(b).

To state a claim under Section 10(b) and Rule 10b-5, a plaintiff must allege: “(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation.” *Pac. Inv. Mgmt. Co. v. Mayer Brown LLP*, 603 F.3d 144, 151 (2d Cir. 2010) (citation omitted).

The CAC includes an extensive list of alleged misstatements and omissions attributed to the Company and Dr. Shendelman, but a generous reading of the pleading shows only three allegedly actionable statements ostensibly attributable to Dr. Perfetti. One of those statements was made by a third-party analyst who did not specify Dr. Perfetti as the source of the information, and another was indisputably made by another symposium panelist—not Dr. Perfetti. As for the only

allegedly actionable statement in the CAC made by Dr. Perfetti, Plaintiff has failed to meet his burden of pleading falsity and materiality. Moreover, as for each of the three statements attributed to Dr. Perfetti, Plaintiff has not met the standard set in the Second Circuit for pleading scienter and loss causation.

A. The Statements Attributed to Company Management in the RBC Report Lack Specificity and Cannot Be Attributed to Dr. Perfetti.

Plaintiff's claims against Dr. Perfetti are based, in part, on alleged misstatements in an August 7, 2024 RBC analyst report attributed to Applied's "mgmt. team." *See* Chapman Decl. Ex. 1; CAC at ¶¶ 207-208. But the RBC Report does not tie the alleged misstatements to any specific individual, and certainly not Dr. Perfetti by name, title, or any other basis. These vague and conclusory allegations fall far short of the heightened pleading requirements under Rule 9(b) and the PSLRA and cannot support a securities fraud claim against Dr. Perfetti.

Courts in this Circuit routinely find that anonymous or unattributed quotes, such as the one in the RBC Report Plaintiff erroneously attributed to Dr. Perfetti, fail to satisfy the heightened pleading standard applicable to fraud and securities law claims. For example, in *In re Time Warner Inc. Sec. Litig.* the Second Circuit held that "anonymous quotes or paraphrases of statements from alleged [corporate] insiders" will not suffice to plead fraud with particularity under Rule 9(b). 9 F.3d 259, 264-65 (2d Cir. 1993). Similarly, in *Total Equity Capital, LLC v. Flurry, Inc.*, this Court dismissed a Section 10(b)(5) claim based on statements attributed to the defendants in an article published by an analyst, where the article did not identify the defendants who allegedly made the statements or show that the defendants were involved in reviewing or approving the article. No. 15-CV-4168 (JMF), 2016 WL 3093993, at *3 (S.D.N.Y. June 1, 2016). Here, as in *Total Equity Capital*, the CAC alleges no facts showing that Dr. Perfetti spoke with RBC, was involved in making the statement, reviewing the statement, approving the statement, or

disseminating the statement in the RBC Report, and that includes no allegations that Dr. Perfetti spoke with RBC about the NDA or regulatory process.

To hold a corporate officer liable for statements in an analyst report, a plaintiff must allege facts demonstrating that the officer either “intentionally fostered a mistaken belief concerning a material fact that was incorporated into reports” or that the officer “adopted or placed their imprimatur on the reports.” *Rombach*, 355 F.3d at 174-75; *accord Liu v. Intercept Pharms., Inc.*, No. 17-CV-7371 (LAK), 2020 WL 1489831, at *6 (S.D.N.Y. Mar. 26, 2020). The CAC contains no such allegations against Dr. Perfetti. Instead, Plaintiff insufficiently relies on a vague attribution to “the mgmt. team.”

Statements generally attributed to “management” may be actionable in some cases, such as where specific officers regularly interact with analysts and are known to have participated in relevant meetings. *See In re Abercrombie & Fitch Co. Sec. Litig.*, No. M21-83 (TPG), 2003 WL 22705131, at *4 (S.D.N.Y. Nov. 17, 2003). However, allegations, such as those in the CAC, that fail to specify who attended analyst meetings or assert claims against officers who neither participated in those meetings nor routinely communicated with analysts are routinely rejected. *See Liu*, 2020 WL 1489831, at *6; *see also Abercrombie*, 2003 WL 22705131, at *4.

This Court’s holding in *Liu* is particularly instructive. The plaintiffs in that case relied on alleged misstatements in analyst reports regarding a drug’s safety and efficacy. *Liu*, 2020 WL 1489831, at *6. The Court held that plaintiffs met their pleading requirement with respect to one statement because the complaint alleged the date the statement was made, the circumstances in which it was made, and identified the speaker. However, the Court held that plaintiffs failed to meet their burden with respect to the other statements because the complaint failed to “identify the speaker and attribute[d] the comments only to ‘management.’” *Id.*

Similarly, in *Abercrombie*, the complaint referred to reports and comments by analysts purporting to quote management. 2003 WL 22705131, at *3. This Court found the plaintiffs' allegations as to one individual defendant insufficient because they failed to allege that "she either made any of the alleged misrepresentations or that she was regularly involved in conveying information to security analysts." *Id.* at 4. Because the CAC does not link the statements in the RBC Report to Dr. Perfetti or allege Dr. Perfetti was regularly involved in conveying such information to securities analysts, the CAC fails to plead an actionable statement in the RBC Report.

B. Dr. Perfetti Was Not the Author or Presenter of Slides Cited by Plaintiff in the September 4, 2024 Presentation Used by Panelists at the SSIEM Symposium.

Setting aside the fact that Plaintiff fails to plead any actionable misstatements in any of the slides presented at the SSIEM Symposium, the securities fraud claim against Dr. Perfetti also fails because Plaintiff does not allege any facts that support the conclusory allegation he "author[ed] or present[ed]" the slides at issue—specifically, slides 40 and 42 through 55 of a 66-slide presentation in which Dr. Perfetti is listed as a presenter along with two other individuals, one of whom is not employed by Applied. *See* Chapman Decl. Ex. 2; CAC at ¶¶ 223-225. That omission is fatal.

As the Supreme Court made clear in *Janus*, liability is generally limited to the maker of the statement and "the maker of a statement is the person or entity with ultimate authority over the statement including its content and whether and how to communicate it." 564 U.S. at 142. In short, "it is the speaker who takes credit—or blame—for what is ultimately said." *Id.* at 143. Merely preparing, editing, or participating in the making of a statement on behalf of someone else does not make one its "maker." *Id.* Nor does reviewing or suggesting edits. *Id.*

Here, Plaintiff attempts to pin liability on Dr. Perfetti for slides he did not author or present. The record indicates another participant—not Dr. Perfetti—was responsible for the slides.⁵ The law is clear: a duty to disclose arises only from a speaker’s own omissions, and a duty to correct arises only “if and when a *speaker* learns that a prior statement was misleading.” *In re IBM Corp. Sec. Litig.*, 163 F.3d 102, 109 (2d Cir. 1998) (emphasis added); *accord Backman v. Polaroid Corp.*, 910 F.2d 10, 16-17 (1st Cir. 1990) (“[I]f a disclosure is in fact misleading when made, and the *speaker* thereafter learns of this, there is a duty to correct it.”) (emphasis added). That duty does not extend outside the speaker “to rectify misstatements of others.” *United States v. Schiff*, 602 F.3d 152, 167 (3d Cir. 2010). Courts consistently reject liability in such scenarios—whether it is a company failing to correct inaccurate press reports not attributable to it (*Elec. Specialty Co. v. Int’l Controls Corp.*, 409 F.2d 937, 949 (2d Cir. 1969)), or one executive not bearing responsibility for another’s misstatements (*Schiff*, 602 F.3d at 162-69), or an accountant not being liable for a corporation’s unaudited statements or press releases about those statements (*Overton v. Todman & Co., CPAs, P.C.*, 478 F.3d 479, 486-87 (2d Cir. 2007)).

Dr. Perfetti’s role as CMO “and key employee of Applied” does not confer “ultimate authority” over Applied’s public disclosures, much less slides from a presentation at a medical symposium that he did not author or present. *Janus*, 564 U.S. at 142. Accordingly, because Dr. Perfetti neither made the statements at issue nor had any duty to correct them, he cannot be found liable for any misstatement in the SSIEM Slides.

⁵ See Dr. Barbara Burton, et al., *Development of Govorestat (AT-007), the First Potential Treatment for Patients with Classic Galactosemia*, at slide 5 (Sept. 4, 2024), Chapman Decl. Ex. 2. On slide 5, it is clear that Dr. Perfetti did not present the slides in question. *Id.*

C. Statements Regarding the Pediatric Study in the November 2024 Article Were Not False or Materially Misleading.

Plaintiff fails to plead with particularity any facts showing Dr. Perfetti misled investors about the results of the Pediatric Study published in the November 2024 Article—or that any of his statements were false as required under Rule 10b-5. For a statement of fact to be actionable under Section 10(b), “the statement must be false and the statement must be material. Neither immaterial false statements nor material true statements are actionable.” *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 571 (S.D.N.Y. 2014) (citing *Basic Inc. v. Levinson*, 485 U.S. 224, 238 (1988)).

As to falsity, a claim for securities fraud premised on a misstatement “cannot occur unless an alleged material misstatement was false at the time it was made.” *Id.* Thus, “[a] statement believed to be true when made, but later shown to be false, is insufficient.” *Id.* Moreover, the Second Circuit has repeatedly stated that plaintiffs must do more than simply assert that a particular statement is false or misleading; rather, “they must demonstrate with specificity why and how that is so.” *Rombach*, 355 F.3d at 174.

In the CAC, Plaintiff does not and cannot point to any alleged misstatements concerning the conduct of the Pediatric Study. Similarly, there is no allegation that the results of the Pediatric Study were inaccurate. Instead, Plaintiff attempts to allege that the Pediatric Study results published in the November 2024 Article were falsely presented as the complete results included in the NDA. *See* CAC at ¶¶ 249-252. In fact, the article does not even mention the NDA, much less represent what the NDA submission included, and therefore Plaintiff cannot meet the requirement of pleading falsity. *See* Chapman Decl. Ex. 3.

As to materiality, courts in this Circuit require plaintiffs to establish a “sufficiently close nexus between the affirmative statement and the alleged omission.” *In re Omega Healthcare*

Investors, Inc., 563 F. Supp. 3d 259, 272 (S.D.N.Y. 2021). In *Omega*, plaintiffs challenged statements made by defendants in a press release about the company’s financial earnings, alleging that defendants’ duty to disclose the company’s deteriorated financial condition and missed rent payments arose from the company’s generic statements regarding industry trends and the company’s overall balance sheet. *Id.* at 272-273. The Court held that plaintiffs could not establish a “sufficiently close nexus between the affirmative statement and the alleged omission to demonstrate that defendants specifically put [the company’s] financial condition and missed rent payments ‘in play’ and thus had a duty to disclose the omitted information.” *Id.*

Here, the November 2024 Article reports on the safety and efficacy of govorestat; it does not make any representations about the likelihood of success of the NDA, or the dosages given to participants during the dose-escalation period of the Pediatric Study. *See* Chapman Decl. Ex. 3. The CAC contains no allegation that the dosages included in the November 2024 Article are inaccurate or in any way relate to the dose-escalation period (where the Dosing Error occurred). Nor does Plaintiff allege that the November 2024 Article contains any representation concerning dosing during the dose-escalation period. Instead, Plaintiff proffers a wholly conclusory allegation, unaccompanied by any support for his factual assertions, regarding what a reasonable investor would infer from specifically described data in a publication for medical professionals with regard to the contents and likely outcome of the NDA. Such generalized, unsupported allegations fail to state a claim. *See ATSI Commc’ns*, 493 F.3d at 99.

D. Plaintiff Has Failed to Plead Scienter.

Even if Plaintiff had identified any materially false statements by Dr. Perfetti, the claims against him must still be dismissed due to the failure to plead a cogent basis for scienter. The scienter pleading requirement demands that, with respect to each allegedly actionable statement, a

plaintiff must “state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind,” *i.e.*, that the defendant intended “to deceive, manipulate, or defraud.” *See* Section 21D(b)(2)(A) of the Exchange Act [15 U.S.C. § 78u-4(b)(2)(A)]; *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 313 (2007). “To qualify as ‘strong’ within the intendment of [the PSLRA] . . . an inference of scienter must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent.” *Tellabs*, 551 U.S. at 314. “A complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.” *Id.* at 324.

Allegations of motive and opportunity must allege that defendants “benefitted in a concrete and personal way from the purported fraud.” *South Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 110 (2d Cir. 2009). Motives that can be ascribed to “virtually all corporate insiders” (*id.* at 109) or “any publicly-owned for-profit endeavor” are not sufficient to support a claim of fraud. *Kalnit v. Eichler*, 264 F.3d 131, 140 (2d Cir. 2001); *Chill*, 101 F. 3d at 26. Examples of general motives which fail to support a strong inference of scienter include “(1) the desire for the corporation to appear profitable and (2) the desire to keep stock prices high to increase officer compensation.” *Kalnit*, 264 F.3d at 139.

1. Plaintiff’s Motive Allegations are Deficient.

Plaintiff attempts to demonstrate “motive and opportunity” by pointing to three ordinary course sales of Applied common stock by Dr. Perfetti during the Class Period, totaling 155,488 shares and yielding \$824,516.74. *See* Chapman Decl. Exs. 4-6; CAC at ¶ 304. Noticeably absent from the CAC, however, is any allegation demonstrating that Dr. Perfetti “made a misrepresentation in order to sell [his] own shares at a profit.” *In re Sanofi Sec. Litig.*, 155 F.

Supp. 3d 386, 405 (S.D.N.Y. 2016) (citing *ECA, Local 134*, 553 F.3d at 198). “The mere fact that insider stock sales occurred does not suffice to establish scienter.” *In re Gildan Activewear, Inc. Sec. Litig.*, 636 F. Supp. 2d 261, 270 (S.D.N.Y. 2009) (citation omitted). To support a strong inference of scienter, a plaintiff must demonstrate, at a minimum, that the sales are “unusual” or “suspicious” in timing or amounts. *See Acito v. IMCERA Grp., Inc.*, 47 F.3d 47, 54 (2d Cir. 1995); *Gildan Activewear*, 636 F. Supp. 2d at 270-71. Plaintiff does not allege a single fact demonstrating that Dr. Perfetti’s stock sales were in any way unusual or suspicious.

First, the same SEC filings on which Plaintiff relies to show Dr. Perfetti’s sales make clear they were “shares sold by [Dr. Perfetti] to cover tax withholding obligations in connection with the vesting settlement of compensatory Restricted Stock Units. The sale was to satisfy tax withholding obligations to be funded by a ‘sell to cover’ transaction and does not represent a discretionary transaction by the reporting person.”⁶ Courts routinely hold that such sales are neither unusual nor suspicious, and therefore they do *not* support a strong inference of scienter. *See, e.g., In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 561 (S.D.N.Y. 2004) (finding that records showing “a consistent pattern of trading undertaken primarily to make payments required for the exercise of stock options or to pay taxes” did not support an inference of scienter); *In re Tyson Foods, Inc. Sec. Litig.*, 275 F. Supp. 3d 970, 1001 (W.D. Ark. 2017) (finding that “stock sold by defendants for tax purposes following the vesting of performance shares” is not at all probative of scienter); *Glaser v. The9, Ltd.*, 772 F. Supp. 2d 573, 592 (S.D.N.Y. 2011) (holding that it is well established that routine, scheduled trades such as “trades under 10b-5-1 plan ‘do not

⁶ *See* SEC Form 4 for Dr. Riccardo Perfetti (Mar. 18, 2024), <https://appliedtherapeutics.gcs-web.com/static-files/43c9ef91-3cbe-4f89-b1ff-54a80b369b9a>, Chapman Decl. Ex. 4; SEC Form 4 for Dr. Riccardo Perfetti (June 10, 2024), <https://appliedtherapeutics.gcs-web.com/static-files/2764f615-0170-408c-8bc3-ad5b68d645f6>, Chapman Decl. Ex. 5; SEC Form 4 for Dr. Riccardo Perfetti (Aug. 23, 2024), <https://appliedtherapeutics.gcs-web.com/static-files/436bf501-cd23-4000-9c43-e3ec48d3ea00>, Chapman Decl. Ex. 6.

raise a strong inference of scienter””) (citation omitted); *Gildan Activewear*, 636 F. Supp. 2d at 272 (same).

Second, the timing of Dr. Perfetti’s three Class Period stock sales does not suggest any connection to the alleged fraud. Courts consistently reject scienter allegations where insider sales are not closely tied to corrective disclosures or other significant market-moving events. *See Gildan Activewear*, 636 F. Supp. at 271 (“Plaintiffs’ allegations are empty vessels, as the trades occurred weeks before the principal allegation of material misstatement, and many months before the release of any negative information”); *In re Sina Corp. Sec. Litig.*, No. 05-CV-2154 (NRB), 2006 WL 2742048, at *12 (S.D.N.Y. Sept. 26, 2006) (finding no inference of scienter “because [] the sales occurred more than a month before” a corrective disclosure). Applied made multiple public disclosures in early 2024, but Dr. Perfetti’s first sale occurred on March 14, 2024, without any alleged connection to a material event. *See* Chapman Decl. Ex. 4; CAC at ¶ 304. His second sale, on June 6, 2024, occurred approximately one month *after* Applied responded to the FDA’s Form 483 and a month *before* Applied’s July 1, 2024 press release announcing Applied had been added to the Russell 3000 Index.⁷ *See* Chapman Decl. Ex. 5; CAC at ¶ 304. Nor is there any alleged connection between his August 23, 2024 sale and a material event; it was well before the September 18, 2024 press release providing a regulatory update, including that the FDA no longer intended to hold an Advisory Committee meeting.⁸ *See* Chapman Decl. Ex. 6; CAC at ¶ 304. These sales were not made “on the eve” of any news and do not fit the pattern of an executive seeking to capitalize on inside information. *See Frazier v. VitalWorks, Inc.*, 341 F. Supp. 2d 142,

⁷ *See generally*, Press Release, Applied Therapeutics Added to Russell 3000 Index (Jul. 1, 2024), Chapman Decl. Ex. 7.

⁸ *See generally*, Press Release, Applied Therapeutics Provides Regulatory Update on Govorestat for the Treatment of Classic Galactosemia (Sept. 18, 2024), Chapman Decl. Ex. 8.

161-62 (D. Conn. 2004) (nine- and seven-week gaps between sales and bad news did not raise a “‘strong inference’ . . . that defendants were trying to sell off stock on the basis of inside information.”).

Indeed, as pled, the CAC lacks any coherence or plausibility. Plaintiff alleges that Applied, Dr. Shendelman, and Dr. Perfetti knew the Pediatric Study results were incomplete and therefore inadequate for FDA approval. CAC at ¶¶ 4, 29, 68, 72, 73, 75. Yet, according to the CAC, Applied nevertheless invested significant time and resources into preparing for commercialization despite allegedly knowing the NDA was destined to fail, and simultaneously misleading the public by suggesting approval was likely. *See* CAC at ¶¶ 9, 16, 191-208. That theory defies common sense, and courts routinely reject such implausible narratives. *See, e.g., Cozzarelli v. Inspire Pharms., Inc.*, 549 F.3d 618, 627 (4th Cir. 2008) (“It is improbable that [Defendant] would stake its existence on a drug and a clinical trial that the company thought was doomed to failure.”); *Johnson v. Pozen*, No. 1:07-CV-599, 2009 WL 426235, at *25 (M.D.N.C. Feb. 19, 2009) (inference of scienter undermined where defendants pointed out that “if they had known in 2006 that the FDA would require an additional study beyond [that included in their application], [they] would have conducted the study then, therefore speeding up FDA approval”).

Nor could the alleged scheme have continued. The FDA’s rejection of the NDA—an inevitable and foreseeable outcome under Plaintiff’s theory—would have publicly exposed any misrepresentations in short order. As one court observed, “the tenuous plausibility of the alleged scheme substantially weakene[d] the overall strength of plaintiffs’ scienter allegations[,] . . . [where defendants] must have . . . realized that . . . [the public would] quickly uncover the scheme.” *In re GeoPharma, Inc. Sec. Litig.*, 411 F. Supp. 2d 434, 446-47 (S.D.N.Y. 2006). The CAC offers

no rational explanation for why Defendants, including Dr. Perfetti, would knowingly incur such a risk.

2. Plaintiff's Allegations of Recklessness are Also Deficient.

Even where a plaintiff fails to plead scienter through motive and opportunity, a securities fraud claim may nonetheless survive if the complaint alleges “strong circumstantial evidence of conscious misbehavior or recklessness.” *Kalnit*, 264 F.3d at 138-39. As set forth in *In re Carter-Wallace, Inc. Sec. Litig.*, “to survive dismissal under the conscious misbehavior theory, the [Plaintiff] must show that they alleged reckless conduct by the [Defendants], which is, at the least, conduct which is highly unreasonable and [] represents an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it.” 220 F.3d 36, 39 (2d Cir. 2000) (internal quotation marks omitted). No such facts are pled in the CAC.

Plaintiff attempts to imply scienter by emphasizing that Dr. Perfetti was aware of the observations from the Form 483⁹ (which had nothing to do with the Dosing Errors) by assuming that, by virtue of his position, the results would have been shared with him by either the FDA or Dr. Shendelman. CAC at ¶ 139. But “positional scienter” is legally insufficient. “[T]o establish an inference of scienter, Plaintiff[s] must do more than allege that the Individual Defendants had or should have had knowledge of certain facts contrary to their public statements simply by virtue of their high-level positions.” *See Lipow v. Net1 UEPS Techs., Inc.*, 131 F. Supp. 3d 144, 163 (S.D.N.Y. 2015); *see also In re Nokia Oyj (Nokia Corp.) Sec. Litig.*, 423 F. Supp. 2d 364, 406

⁹ *FDA Form 483 Frequently Asked Questions*, U.S. Food & Drug Admin., <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions> (last visited May 23, 2025) (“The FDA Form 483 does not constitute a final Agency determination[.]”). *See* CAC at ¶ 140.

(S.D.N.Y. 2006). Courts in this Circuit have consistently held that “accusations founded on nothing more than a defendant’s corporate position are entitled to no weight.” *City of Brockton Ret. Sys. v. Avon Prod., Inc.*, No. 11-CV-4665 (PGG), 2014 WL 4832321, at *19 (S.D.N.Y. Sept. 29, 2014) (citation omitted); *see also In re Checkpoint Therapeutics Sec. Litig.*, No. 24 Civ. 2613 (PAE), 2025 WL 1434400, at *25 (S.D.N.Y. May 19, 2025) (rejecting complaint’s “attempt to derive scienter from the fact that a defendant is a ‘key officer’ well versed in a company’s business” due to case law which “reject[s] the premise of ‘*ex officio* omniscience of all business risks”).

Here, Plaintiff relies on the conclusory assertion that, because of his role at Applied, Dr. Perfetti must have been aware of the issues in the Form 483. This type of speculation—untethered to specific facts regarding meetings, documents, or witness accounts—does not support a strong inference of scienter under PSLRA. *See Plumbers & Steamfitters Local 773 Pension Fund v. Canadian Imperial Bank of Com.*, 694 F. Supp. 2d 287, 300 (S.D.N.Y. 2010) (“[A]ccusations founded on nothing more than a defendant’s corporate position are entitled to no weight.”); *Checkpoint*, 2025 WL 1434400, at *26 (“The AC’s allegations do not ‘support the probability that a person in [Defendant’s] position . . . would possess the information alleged.’”) (citation omitted).

3. Plaintiff Impermissibly Relies on “Group Pleading” to Infer Scienter Against Dr. Perfetti.

The Court should also reject Plaintiff’s attempt to allege scienter against Dr. Perfetti through impermissible group pleading. Under Rule 9(b), “plaintiffs must plead circumstances providing a factual basis for scienter for each defendant; guilt by association is impermissible.” *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 695 (2d Cir. 2009); *C.D.T.S. v. UBS AG*, No. 12-CV-4924 (KBF), 2013 WL 6576031, at *6 (S.D.N.Y. Dec. 13, 2013), *aff’d sub nom. Westchester Teamsters Pension Fund v. UBS AG*, 604 F. App’x 5 (2d Cir. 2015).

Plaintiff impermissibly lumps Drs. Shendelman and Perfetti together, citing a broad array of statements in SEC filings, press releases, and investor communications, the overwhelming majority of which Dr. Perfetti is not alleged to have made, without making any individualized allegations of scienter.¹⁰ CAC at ¶¶ 78, 79, 89, 90, 97-99, 103, 105, 111, 115, 116, 122, 146, 150, 151, 155, 157, 164, 166, 170, 171, 180, 182, 193-196, 198, 204, 205, 227-231, 237, 239, 255-258, 264, 266. The CAC does not allege that Dr. Perfetti played any role in authoring, reviewing, or approving these group-published materials. This failure is fatal under well-settled law. *In re Keyspan Corp. Sec. Litig.*, 383 F. Supp. 2d 358, 388 (E.D.N.Y. 2003) (dismissing securities fraud claim where plaintiffs’ conclusory and vague allegations failed to show specific information that contradicted individual defendants’ statements).

4. Plaintiff Fails to Adequately Plead Scheme Liability.

Count I of the CAC alleges that Defendants, including Dr. Perfetti, “individually and in concert” made false and misleading statements and engaged in a scheme to defraud investors in violation of Section 10(b) and Rule 10b-5(a) and (c) thereunder. CAC at ¶¶ 381-382. To state such a claim, a plaintiff must show, among other things, “(1) that the defendant committed a deceptive or manipulative act, (2) in furtherance of the alleged scheme to defraud, (3) with scienter, and (4) reliance.” *Plumber & Steamfitters Local 773 Pension Fund v. Danske Bank A/S*, 11 F.4th 90, 105 (2d Cir. 2021) (citation omitted). Rule 9(b) further requires that “a plaintiff must specify what deceptive or manipulative acts were performed, which defendants performed them, when the acts were performed, and the effect the scheme had on investors in the securities at issue.” *See In*

¹⁰ The phrase “Dr. Shendelman and Applied” is used 60 times in the CAC. “Dr. Perfetti and Applied” is used once with regard slides 40-42 published about the Pediatric Study from the presentation of the SSIEM Slides. CAC at ¶ 225.

re CarLotz, Inc. Sec. Litig., 21-CV-5906 (AS), 2024 WL 3924708, at *2 (S.D.N.Y. Aug. 23, 2024).

Plaintiff, unaided by any fact in support, primarily contends that Dr. Perfetti, “by virtue of [his] receipt of information reflecting the true facts of Applied, [his] control over, and/or receipt and/or modification of Applied’s allegedly materially misleading statements, and/or [his] associations with the Company which made [him] privy to confidential propriety information concerning Applied” engaged in a fraudulent scheme by making and disseminating materially false or misleading statements which “(i) deceive[d] the investing public . . . ; (ii) artificially inflate[d] and maintain[ed] the market price of Applied common stock; and (iii) caused Plaintiff . . . to purchase or otherwise acquire Applied common stock at artificially inflated prices.” CAC at ¶¶ 382, 385.

However, established law in this Circuit “require[s] scheme claims to be premised on deceptive acts that are distinct from misstatements and omissions that underlie an accompanying Rule 10b-5 claim.” *Danske Bank A/S*, 11 F.4th at 105 n.6 (collecting cases); *see also In re Mindbody, Inc. Sec. Litig.*, 489 F. Supp. 3d 188, 217 (S.D.N.Y. 2020) (no scheme liability where claim was “indistinguishable from the misstatements and omissions alleged under [the Rule 10b-5 claim]”). While “misstatements and omissions can form part of a scheme liability claim, . . . an actionable scheme liability claim also requires something beyond misstatements and omissions, such as dissemination.” *Sec. & Exch. Comm’n v. Rio Tinto plc*, 41 F.4th 47, 49 (2d Cir. 2022).

In support of his scheme liability claim, Plaintiff simply repeats his insufficient allegations that Dr. Perfetti *made* fraudulent statements in: (1) an analyst report which referenced a conversation with the “mgmt.. team,” (2) a few slides in a multi-slide presentation which Dr. Perfetti neither authored nor presented, and (3) study results published in a highly technical medical journal for reference by medical and scientific professionals. But, “[a]bsent some sort of

enumeration of which specific acts constituted an alleged scheme in connection with the purchase or sale of securities, [Plaintiff's] claim does not comply with the applicable heightened pleading standard and cannot go forward.” *Carlotz*, 2024 WL 3924708, at *4 (citation omitted).

Plaintiff's failure to plead an inherently deceptive or manipulative act separate and apart from the false statements is fatal to his claim of scheme liability. Accordingly, Plaintiff has failed to plead Dr. Perfetti engaged in a scheme to defraud investors in violation of Section 10(b) and Rule 10b-5(a) and (c) thereunder, and his claims against Dr. Perfetti must be dismissed.

E. Plaintiff Has Failed to Plead Loss Causation.

To adequately plead loss causation, a plaintiff must allege that the purported fraudulent statement or omission was the cause of their claimed loss. *See Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 173 (2d Cir. 2005); *see also In re Shanda Games Ltd. Sec. Litig.*, 128 F.4th 26, 57 (2d Cir. 2025). While they need not rule out every alternative cause, a plaintiff must still allege facts showing they would have avoided some or all of their loss but for the fraud. *Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 189 (2d Cir. 2015).

Plaintiff does not come close to meeting this burden. Rather than plead facts showing the requisite causal link for *each* alleged misrepresentation, *see Castillo v. Dean Witter Discover & Co.*, No. 97-CV-1272 (RPP), 1998 WL 342050, at *5 (S.D.N.Y. June 25, 1998), Plaintiff lumps all challenged statements together and claims he suffered losses “when the true facts were disclosed to the market,” after the Company disclosed the issuance of the CRL. CAC at ¶ 31. But the CRL did not correct or contradict any of Dr. Perfetti's statements, nor did it reveal any previously undisclosed falsehoods in Dr. Perfetti's interpretation of the Pediatric Study data. Indeed, Plaintiff does not allege Dr. Perfetti spoke publicly about the NDA or its likelihood of

success, and Applied expressly disclosed the risk that the FDA might not agree with its interpretation of the Pediatric Study data.¹¹

A stock price drop alone is not enough. The decline following the CRL reflects the materialization of a known regulatory risk—not the exposure of hidden fraud. Courts are clear: known risks coming to pass do not establish loss causation. *Monroe Cnty. Emps.’ Ret. Sys. v. YPF Sociedad Anonima*, 15 F. Supp. 3d 336, 358 (S.D.N.Y. 2014), accord *In re CRM Holdings, Ltd. Sec. Litig.*, No. 10-CV-975 (RPP), 2012 WL 1646888, at *30-31 (S.D.N.Y. May 10, 2012).

Accordingly, Plaintiff has not alleged that the purported misstatements were the proximate cause of his loss, and his claims fail for lack of loss causation.

II. Plaintiff’s Section 20(a) Claim Against Dr. Perfetti Fails as a Matter of Law.

Plaintiff asserts a claim under Section 20(a) of the Exchange Act, alleging that Dr. Perfetti is liable as a “control person.” *See* 15 U.S.C. § 78t(a). To state a Section 20(a) claim, a plaintiff must plead “(1) a primary violation by the controlled person, (2) control of the primary violator by the defendant, and (3) that the defendant was, in some meaningful sense, a culpable participant in the controlled person’s fraud.” *Enzo Biochem, Inc. v. Harbert Discovery Fund, LP*, No. 20-CV-9992 (PAC), 2021 WL 5854075, at *8 (S.D.N.Y. Dec. 9, 2021) (quoting *ATSI Commc’ns*, 493 F.3d at 108). This claim fails for at least two reasons.

First, Plaintiff has not pled any facts showing Dr. Perfetti had any control over the Company. The title of Chief Medical Officer alone does not support an inference that Dr. Perfetti controlled the Company, much less with regard to the statements at issue. *See In re Alstom SA Sec. Litig.*, 406 F. Supp. 2d 433, 502 (S.D.N.Y. 2005). The CAC does not point to any press

¹¹ *See generally*, Press Release, Applied Therapeutics Provides Regulatory Update on Govorestat for the Treatment of Classic Galactosemia (Sept. 18, 2024), Chapman Decl. Ex. 8.

release, earnings call transcript, or analyst report that specifically attributes any statement to Dr. Perfetti. Nor did he certify or sign any Company SEC filing. *See, e.g., Flag Telecom Hldgs., Ltd. Sec. Litig.*, 352 F. Supp. 2d 429, 457 (S.D.N.Y. 2005) (concluding that officers or directors who signed a registration statement controlled the company at time of the company's IPO; but dismissing control-person claims against individuals who did not sign a registration statement); *In re Philip Servs. Corp. Sec. Litig.*, 383 F. Supp. 2d 463, 485 (S.D.N.Y. 2004) (holding that directors who also signed a registration statement controlled those who wrote the report); *In re Livent, Inc. Noteholders Sec. Litig.*, 151 F. Supp. 2d 371, 437 (S.D.N.Y. 2001) (holding that a director and audit committee member who signs an SEC filing is presumed to have the power to control those who write the report).

Second, Plaintiff alleges no facts showing that Dr. Perfetti had actual power or control over any alleged wrongdoer. *Cohen v. Stevanovich*, 722 F. Supp. 2d 416, 435 (S.D.N.Y. 2010). Officer status alone is insufficient. *In re Global Crossing, Ltd. Sec. Litig.*, No. 02-CV-910 (GEL), 2005 WL 1907005, *12 (S.D.N.Y. Aug. 8, 2005). Vague claims that a defendant was a “decision-making official” or had “access to material information” are also insufficient. *In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 572 (S.D.N.Y. 2011).

To survive dismissal, Plaintiff must show Dr. Perfetti not only had control over the alleged primary violator, but also over the specific misstatements at issue. *Alstom*, 406 F. Supp. 2d at 487. Plaintiff has not pled any facts showing that Dr. Perfetti (Applied's Chief Medical Officer) controlled Dr. Shendelman (Applied's founder and former CEO, President, Secretary, and Chair of the Board of Directors), who is the only other individual defendant alleged to have made a false or misleading statement and who *outranked* Dr. Perfetti. *In re SunEdison Sec. Litig.*, 300 F. Supp. 3d 444, 497 (S.D.N.Y. 2018) (dismissing controlling person claim against company's CFO where

alleged primary violator was company's CEO and a board member). Plaintiff's Section 20(a) claim is therefore insufficient as a matter of law.

CONCLUSION

For the reasons set forth above, the Court should dismiss the claims in the CAC against Defendant Riccardo Perfetti with prejudice.

Dated: New York, New York
May 23, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 23rd day of May, 2025, I electronically filed the foregoing document with the Clerk of Court by using the CM/ECF system, which will automatically send an email notification of such filing to all attorneys of record in the above-referenced case.

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